

Instructions to request authorized access to GAIN project datasets

This document contains the instructions for submitting a Data Access Request for a Genetic Association Information Network (GAIN) project dataset(s). A complete request includes the following items:

1. Information about your institution, including contact information for you and your Institutional Signing Official. NOTE: A graduate student cannot be listed as the Principal Investigator on a Data Access Request. A post-doctoral student may be listed as the Principal Investigator only when at least one senior mentor (i.e. professor or senior-level researcher) from the same institution is listed as a collaborator.
2. Brief description of your research objectives, design, and analysis plan through the Research Use Statement (see "Preparing the Research Use Statement" below for specific details).
3. A non-technical summary of your proposed research to communicate to the general public the purpose and objectives of your research.
4. Information about collaborators at your local institution. Collaborators at different institutions must submit separate Data Access Requests for access to individual-level data. Only include collaborators at your institution in the "Collaborators" section of the request (Research & Related Senior/Key Person Profile).
5. Information about the IT Director or his/her designee at your local institution, included in the "Collaborators" section of the request. The IT Director or his/her designee is someone with the authority to vouch for the IT capacities at your institution, or higher-level division of an institution (e.g., the School of Medicine). The inclusion of the IT Director or designee is a requirement for access to GAIN data, and is described under the GAIN Data Use Certification dated December 3, 2008, which you and your Institutional Signing Official agree to when submitting your request.
6. Review of and agreement to the terms and statements outlined in the GAIN Data Use Certification (appended to the SF424 (R&R) and also available at <http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?id=phs000019>).
7. Review and approval of the Data Access Request by your Institutional Signing Official.

These 7 items are included in the SF424 (R&R) generated by the dbGaP request system.

Note: Prior approval for a GAIN dataset does not cover use of this dataset in a new project. If you plan to combine datasets from a previously approved project with a new set of requested datasets, all datasets that will be used **must** be selected as part of the project, even if you were previously approved to use these datasets under a different project.

Preparing the Research Use Statement [SF 424 (R&R), page 3]

- If, in addition to requesting a GAIN project dataset (s), you are requesting other dataset(s) that are not part of GAIN, your Data Access Request will be reviewed by the

Data Access Committee(s) for all NIH Institutes and Centers that are responsible for datasets included within your access request. The responsible Institute and Centers may have additional requirements for requesting data or different terms of access. Be sure to read the Instructions and Data Use Certification document for all requested datasets.

- The GAIN Data Access Committee will compare the Research Use Statement to the **Use Restrictions** for the dataset(s) to confirm that the proposed research is consistent with the use restrictions provided by the institution that submitted the dataset.
- Both the Research Use Statement and the non-technical summary, which document the uses for which researchers have been allowed to access genetic and phenotypic data, will be included on the dbGaP website to describe your research project to the public.

Tip: Prepare and save the Research Use Statement and the non-technical summary in a word processing application. These statements can be copied and pasted into their respective form boxes during the dbGaP request process. The statements will be inserted into page 3 of the SF424 (R&R) application form.

The Research Use Statement should be 1-2 paragraphs and include:

1. the research objectives,
2. the study design,
3. the analysis plan (including the phenotypic characteristics that will be tested for association with genetic variants),
4. an explanation of how the proposed research is consistent with *Use Restrictions* for the requested dataset(s)
5. an acknowledgement of the *Use Restrictions* and intention to abide by them, and
6. if relevant, a brief description of any planned inter-institutional collaborative research including the name of the collaboration and/or the individual investigators and their institutions. Data cannot be shared with these collaborators until they have submitted a similar request from their own institution and have been approved for access to the datasets. All data security practices outlined in the GAIN Data Use Certification and the [dbGaP Security Best Practices](#) are expected to be followed for the collaborative research project.

If the phenotypic characteristics you plan to evaluate were not the primary focus of the original study (e.g., you propose to create a new outcome variable from existing variables), describe the new outcomes and explain how they are consistent with the Use Restrictions for the dataset being requested.

If you intend to use a dataset or multiple datasets to develop or evaluate performance of new analytical methods, include a sentence indicating how this work is relevant to the specific disease datasets being studied, such as: This methodological work will advance the understanding of the genetic basis of each of the primary conditions included in the requested datasets.

Special care should be taken when requesting datasets from more than one study.

1. Make it clear whether you plan to combine data from the studies for your analyses and focus on outcomes or hypotheses that weren't the primary focus of the original study, or analyze the datasets separately with a focus on the primary study outcomes.

2. If you are focusing on outcomes or hypotheses that weren't the primary focus of the original studies, describe the outcomes you propose to use and state how your proposed use is consistent with any Use Restrictions for each of the requested datasets.
3. If you are combining datasets from more than one study for your analyses, discuss whether this creates any additional risks to participants.

Research & Related Senior/Key Person Profile [SF 424 (R&R), page 4+]

- List all the collaborating investigators and the IT Director or his/her designee at your organization. By submitting an individual's name on the form, requestors and Institutional Signing Officials affirm that the collaborators have read and agreed to the terms and statements within the Data Use Certification.
- At a minimum, you are required to complete the "name", "position/title", and "organization name" information fields for each collaborator listed.
- Your collaborators at different organizations must complete separate requests for the data.
- Coordinated requests by collaborating organizations should have the same request title and each should reference the collaboration in the Research Use Statement.